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May 2, 2017

***VIA ELECTRONIC COURT FILING***

The Honorable Gary L. Sharpe, Chief Judge  
U.S. District Court, Northern District of New York  
James T. Foley - U.S. Courthouse  
445 Broadway  
Albany, NY 12207

**Re: *Alleyne, et al. v. New York State Education Department, et al.*;  
N.D.N.Y. No. 1:06-CV-994 (GLS)**

Dear Judge Sharpe:

Please accept this letter as Plaintiffs' status report on the progress of the Judge Rotenberg Educational Center, Inc.'s ("JRC") 510(k) application, filed pursuant to the Court's Orders, dated May 29, 2013 and April 11, 2016. As previously reported to the Court, on January 9, 2013 the U.S. Food and Drug Administration ("FDA") asked JRC to file with the FDA a pre-510(k) submission, which JRC did on February 1, 2013. After JRC filed the pre-510(k), the FDA requested that JRC give the FDA an opportunity to review the pre-510(k) submission before JRC files the 510(k) application. The FDA has not responded to JRC's pre-510(k) submission.

On April 1, 2014, JRC was informed by the FDA "that The Center for Devices and Radiological Health (CDRH), Neurological Devices Panel of the Medical Devices Advisory Committee of the Food and Drug Administration, will be holding an advisory committee meeting for Thursday, April 24, 2014 at Holiday Inn, Main Ballroom, 2 Montgomery Village Ave in Gaithersburg, MD to discuss the current knowledge about the safety and effectiveness of aversive conditioning devices. The Agency is considering whether to ban aversive conditioning devices that are intended to administer a noxious electrical stimulus to a patient to modify undesirable behavioral characteristics." The FDA's "Summary of the Neurological Devices Panel Meeting" is posted at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/NeurologicalDevicesPanel/UCM395022.pdf>. On April 22, 2016, the FDA announced a proposal to ban electrical stimulation devices intended to treat self-injurious or aggressive behavior. The FDA's proposed rule is posted at <https://www.federalregister.gov/articles/2016/04/25/2016-09433/banned-devices-proposal-to-ban-electrical-stimulation-devices-used-to-treat-self-injurious-or>. The proposed rule was subject to a public comment period, which ran through July 25, 2016. The FDA's proposed rule states that "[t]he purpose of this proposed rule is to



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seek comments on these determinations as well as seek comments on FDA's proposal to ban ESDs used for SIB or AB and comments on any other associated issues." At this time, it is unclear whether the proposed rule will be approved and/or in what form.

Plaintiffs would also like to alert the Court that only one of the Plaintiffs currently receives treatment with an electrical stimulation device, the Graduated Electronic Decelerator, and he is transitioning from special education services to adult services on July 1, 2017. On or after July 1, 2017, the Parties have agreed to file a Stipulation of Voluntary Dismissal with Prejudice pursuant to Fed. R. Civ. P. 41(a)(1)(A)(ii), with each Party bearing its own attorneys' fees and costs.

If you need anything further, then please contact me. Thank you.

Very truly yours,

/s/ Michael P. Flammia

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cc: Jeffery J. Sherrin, Esq. (by electronic court filing)  
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